UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Allergan PLC Securities Litigation	No. 18-cv-12089-CM CLASS ACTION JURY TRIAL DEMANDED This Document Relates To: All Actions

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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Lead Plaintiff Boston Retirement System, on behalf of itself and all others similarly situated, alleges the following based upon personal knowledge as to its own acts and upon information and belief as to all other matters based on the investigation conducted by Lead Counsel, which included a review of, *inter alia*, SEC filings by Allergan plc ("Allergan" or the "Company"), press releases and other public statements by Defendants, conference calls and announcements made by Defendants, media and analyst reports and advisories about the Company, interviews with confidential witnesses, and other public information. Lead Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

PRELIMINARY STATEMENT

1. This is a federal securities class action, against the Company and certain of its executive officers, on behalf of all persons who purchased or otherwise acquired the Company's securities between January 30, 2017 and December 19, 2018, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

2. Allergan is a global pharmaceutical company engaged in the development, manufacturing, marketing, and distribution of branded pharmaceutical and medical-aesthetics products. In particular, Allergan offers silicone gel breast implants for use in breast-augmentation and breast-reconstruction procedures.

3. Anaplastic large cell lymphoma ("ALCL") is a rare type of non-Hodgkin lymphoma. Breast implant-associated ALCL ("BIA-ALCL") is, as the name would suggest, ALCL that develops in women with breast implants. The first case of BIA-ALCL was diagnosed

in 1997. The association between breast implants and ALCL gained significant attention in 2008 when certain medical research studies were published expounding on the link.

4. In March 2015 (published online on December 8, 2014) a major analysis of the breast implant and ALCL connection was published. More importantly, the study determined that out of 170 breast implants, in 61 cases the manufacturer was unknown, yet in 97 cases (or 56%) the implants were Biocell Allergan/Inamed/McGhan. By far, the largest percentage of implants with BIA-ALCL were manufactured by Allergan/Inamed/McGhan.

5. In July 2015, Drs. Mollie Carter and Joseph Purpora, employees of Allergan, submitted a letter to the editor of the Plastic Reconstructive Surgery Journal, commenting on the March 2015 article. The letter stated, "We read with great interest [the articles] and the associated discussions for both articles…Allergan remains interested in elucidating the cause, diagnosis, and treatment of breast implant–associated anaplastic large cell lymphoma and is committed to supporting this important research."

6. On May 19, 2016, the World Health Organization ("WHO") issued a guidance definitely linking breast implants to ALCL and officially named the disease "breast implant associated ALCL."

7. Since the WHO's May 2016 guidance, ample evidence has accumulated showing that BIA-ALCL is a unique disease that requires unique management and therapeutic approaches and is under-recognized and under-reported. More studies have been published which consistently demonstrate that there is a link, not only just between breast implants and the development of ALCL, but specifically between Allergan's textured implants (Natrelle 410 and Biocell) and the development of BIA-ALCL. For example, a study published in January 2017

(published online on December 28, 2016) found an incidence rate for development of BIA-ALCL, in patients of Natrelle 410 implants, to be ***close to 1 in 4,000***.

8. The Class Period begins on January 30, 2017, when ABC News 7 on Your Side published an article titled, "Woman who beat cancer once says breast implants caused cancer again." In the article, Defendant Frances DeSena, is quoted as stating:

> ***Lastly, to reiterate, Allergan has a robust post-market surveillance process (e.g., collecting reports of BIA-ALCL from surgeons, notifying FDA and other international regulatory agencies of all suspected cases***, monitoring literature and case presentations, etc.) to monitor and report suspected cases of BIA-ALCL.
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> ***
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> ***Allergan is actively working to help advance the knowledge of this disease,*** understand the association of BIA-ALCL and textured implants, and educate the community.[1]

9. In the article, Defendant Mark Marmur, is quoted as stating: "***Allergan is actively working to help advance the knowledge of this disease***, understand the association of BIA-ALCL and textured implants, and educate the community."

10. Throughout the Class Period, Defendants made similar materially false and misleading statements, in press releases, earnings calls, conferences, to news organizations and in their regulatory filings, which failed to disclose material adverse facts regarding the Company's business, operational, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose:

i. that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated by various medical studies,

[1] All emphasis supplied unless otherwise noted.

ii. that the Company and the Individual Defendants knew of, or recklessly disregarded, the link to ALCL;

iii. that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from certain markets;

iv. that while publicly claiming that they were serious about researching the BIA-ALCL link, the company shut down its Santa Barbara facility, which was the center of breast implant research and development;

v. that they did not disclose in its FDA-mandated follow-up study the reports of BIA-ALCL Allergan had received;

vi. that Allergan failed to report many adverse events individually and publicly and instead used inappropriately nonpublic "Alternative Summary Reports" and the Company submitted at least one case of possible BIA-ALCL through an alternative summary report;

vii. that by suppressing the reporting of adverse event reports Defendants knew or recklessly disregarded the risk that some BIA-ALCL cases would go undetected by the FDA, which contradicts their statements of being in compliance with FDA reporting guidelines;

viii. that, as detailed in various consumer complaints, Allergan was not appropriately advising patients of the risks associated with textured breast implants and the development of BIA-ALCL.

11. On December 18, 2018, France's National Agency for the Safety of Medicines & Health Products ("ANSM") ordered the recall of textured breast implants manufactured by Allergan from the European market, stating that the implants "have been linked to a rare form of

cancer"—specifically, anaplastic large cell lymphoma. On December 19, 2018, Allergan stated that it would remove its textured breast implants from the European market.

12. Following these announcements, Allergan's stock price fell $10.20, or nearly 7%, to close at $136.56 on December 19, 2018.

13. The Individual Defendants were aware of, or recklessly disregarded, the serious and known link between Allergan's textured implants and BIA-ALCL. While concealing these adverse facts from investors, two of the Individual Defendants, Paul Bisaro and William Meury, unloaded substantial amounts of their Allergan stock holdings, collectively reaping approximately $28.7 million in illicit proceeds.

14. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

15. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

16. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

17. Venue is proper in this District under Section 27 of the Exchange Act and 28 U.S.C. § 1391(b), as the Company's stock trades on the New York Stock Exchange in this District.

18. In connection with the acts alleged herein, Defendants directly or indirectly used the means and instrumentalities of interstate commerce, including but not limited to the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

Plaintiff

19. Lead Plaintiff Boston Retirement System acquired the Company's securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

Defendants

20. Defendant Allergan plc ("Allergan" or the "Company") is an Irish corporation with its principal executive offices at Clonshaugh Business and Technology Park, Coolock, Dublin, D17 E400, Ireland. Its administrative headquarters in the United States are at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

21. Defendant Brenton L. Saunders is Chairman, President and Chief Executive Officer of Allergan and has served in the role of President and Chief Executive Officer since July 2014 and of Chairman since October 2016, having previously served as Chief Executive Officer and President, and as director, of Forest Laboratories, Inc., prior to its acquisition by Allergan. Prior to that, he served as Chief Executive Officer of Bausch + Lomb Incorporated, a leading global eye health company, serving in this capacity from March 2010 until August 2013. Mr. Saunders also held a number of leadership positions at Schering-Plough, including the position of President of Global Consumer Health Care, and was named head of integration for the company's merger with Merck & Co. and for Schering-Plough's acquisition of Organon BioSciences. Before joining Schering-Plough, Mr. Saunders was a Partner and Head of

Compliance Business Advisory at PricewaterhouseCoopers LLP. Prior to that, he was Chief Risk Officer at Coventry Health Care and Senior Vice President, Compliance, Legal and Regulatory at Home Care Corporation of America. Mr. Saunders began his career as Chief Compliance Officer for the Thomas Jefferson University Health System. Mr. Saunders serves on the Board of Directors of Cisco Systems, Inc., RWJBarnabas Health and the Allergan Foundation, and is a member of the Business Council, the Business Roundtable and PhRMA.

22. Defendant Maria Teresa Hilado was the Chief Financial Officer of Allergan from December 2014 until February 2018. Prior to joining Allergan, she served as Senior Vice President, Finance and Treasurer of PepsiCo, Inc. from 2009 to 2014 and as Vice President and Treasurer for Schering-Plough Corporation from 2008 to 2009. Before joining Schering-Plough, she spent more than 17 years with General Motors Corporation in leadership roles of increasing responsibility, including as Assistant Treasurer from 2006 to 2008 and CFO, GMAC Commercial Finance LLC from 2001 to 2005.

23. Defendant Matthew M. Walsh is Executive Vice President and Chief Financial Officer of Allergan and has served in this role since February 2018. Prior to joining Allergan, Mr. Walsh served as EVP, CFO at Catalent for 10 years. Before Catalent, Mr. Walsh was President, CFO and Acting CEO at Escala Group, Inc. He previously held a variety of finance leadership roles at GenTek, Inc., including Vice President-Finance & Chief Financial Officer, Vice President & Treasurer and Group Controller. Mr. Walsh is a CFA® charterholder. He received an MBA from Cornell University, SC Johnson School of Management and a Bachelor of Science in Chemical Engineering from Cornell University, College of Engineering.

24. Defendant Frances DeSena is a Vice President in Allergan's United States Brand and Research and Development Communication division. She has been in this role since December 2016.

25. Defendant Mark Marmur is an Associate Vice President in Allergan's International Communications and Press Relations division. He has been in this role since March 2019. Prior to that he was an Executive Director until February 2018 in the International Communications and Press Relations division. Prior to that he was a Director in Corporate Affairs from March 2015 through February 2018.

26. Defendant Paul Bisaro was a Director on Allergan's Board of Directors from December 31, 2016 to August 29, 2018. Prior to that he served as Executive Officer of Allergan until December 31, 2016. Prior to that he served as Executive Chairman of the Board of Directors until October 26, 2016. Prior to that he served as Actavis's Chief Financial Officer and Chairman at Allergan once it merged with Actavis.

27. Defendant William Meury is Executive Vice President and Chief Commercial Officer of Allergan and has served in this role since May 2016, having previously served as President, Branded Pharma from March 2015 and Executive Vice President, Commercial, North American Brands from July 2014.

28. Together, Defendants Saunders, Hilado, Walsh, Bisaro, Meury, DeSena and Marmur are sometimes referred to herein as the "Individual Defendants." The Individual Defendants possessed the power and authority to control the contents of the Company's SEC filings, press releases, comments to news organizations and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance, and had the ability

and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

RELEVANT NON-PARTIES

29. Confidential Witness #1 ("CW1") was a Senior Project Manager for Allergan from June 2010 to November 2014, based at the Company's Santa Barbara, CA, facility.

30. Confidential Witness #2 ("CW2") was a Biological Research Associate III at Allergan from December 2014 to June 2017, based in the Company's Irvine, CA facility. Prior to that, CW2 was a Senior Research Associate at Allergan from 2010 to December 2014, based in the Company's Santa Barbara facility.

31. CW2 was part of a team of researchers who conducted tests and studies on the Company's products and during all of CW2's tenure at Allergan, CW2 was in the breast implant team.

FACTUAL BACKGROUND

The Company

32. Allergan is a global pharmaceutical company engaged in the development, manufacturing, marketing, and distribution of branded pharmaceutical and medical-aesthetics products, including silicone-gel breast implants for use in breast-augmentation and breast-reconstruction procedures.

33. Allergan and its predecessor companies have been involved in the breast-implant business since 1974, when McGhan Medical Corporation was formed. McGhan Medical Corporation later changed its name to Inamed Corporation. In March 2006, Allergan purchased substantially all of Inamed Corporation. Inamed was a global surgical and medical device company engaged in the development, manufacturing and marketing of plastic and reconstructive surgery products, including breast implants for cosmetic augmentation and breast implants for reconstructive surgery following a mastectomy.

34. From 2013 to 2015, the Company's name was "Actavis plc" and its stock traded on the NYSE under the symbol "ACT." On March 17, 2015, the Company acquired Allergan, Inc. for $77.0 billion. On June 15, 2015, the Company changed its corporate name to "Allergan plc" and changed its ticker symbol to "AGN."

Medical Device Regulations

35. Breast implants are subject to various regulations in different countries.

36. In the United States, breast implants are "medical devices" and are regulated by the Food and Drug Administration ("FDA") under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 301 *et seq.*, to the Federal Food, Drug, and Cosmetics Act of 1938, 52 Stat. 1040.

37. The FDA categorizes medical devices into one of three regulatory classes—Class I, Class II, or Class III—based on the level of risk and the "level of control necessary to provide reasonable assurance of its safety and effectiveness."[2]

[2] *See* U.S. FDA, *Overview of Medical Device Regulation: Regulatory Controls (Medical Devices)*, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls.

38. Class I devices pose a "low to moderate risk" and are subject only to "general controls" such as labeling requirements. 21 U.S.C. § 360c(a)(1)(A). Class II devices pose a "moderate to high risk" to the patient and are therefore subject not only to "general controls" but also to "special controls" such as special labeling requirements, mandatory performance standards, post-market surveillance, and patient registries. *See* 21 U.S.C. § 360c(a)(1)(B). Around 90% of medical devices are either Class I or Class II devices.

39. But if a device either "presents a potential unreasonable risk of illness or injury" for which general controls and special controls are insufficient to provide reasonable assurance of the safety and effectiveness of a device, or are "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," then it is a Class III device and is therefore subject to the highest level of regulatory oversight. 21 U.S.C. §360c(a)(1)(C).

40. Most significantly, Class III devices must receive premarket approval ("PMA") from the FDA before being marketed to the public. To win premarket approval, the manufacturer of a Class III device must provide the FDA with a "reasonable assurance" that the device is both safe and effective. 21 U.S.C. § 360e(c)(1)–360e(d)(2). To do so, a manufacturer "must submit a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 109 (2d Cir. 2006) (citing 21 U.S.C. § 360e(c)), *aff'd*, 552 U.S. 312 (2008).

41. The FDA may approve marketing of the Class III device subject to additional post-approval conditions. *See* 21 U.S.C. §§ 360c-360j; 21 C.F.R. §§ 814.80, 814.82. If a manufacturer fails to comply with the post-approval conditions, the FDA can impose remedies such as additional warnings or corrective labeling and can even withdraw premarket approval. *See* 21 U.S.C. §§ 351, 352, 360(h), 374.

42. More generally, the FDA can withdraw premarket approval "based on newly reported data or existing information" and it "***must withdraw***" premarket approval "if it determines that a device is unsafe or ineffective under the conditions in its labeling." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319–20 (2008) (citing 21 U.S.C. § 360e(e)1)).

43. Even after winning premarket approval, manufacturers of Class III devices are subject to an ongoing obligation to comply with Medical Device Reporting ("MDR") requirements. 21 U.S.C. § 360i(a)(1); 21 C.F.R. § 803.50(a). Most significantly, MDR requires manufacturers to file ***adverse event reports***. Specifically, manufacturers must

> (1) Submit ***reports of individual adverse events*** no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.
>
> (2) Submit ***reports of individual adverse events*** no later than 5 work days after the day that you become aware of:
>
> > (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health or
> >
> > (ii) A reportable event for which we made a written request.
>
> (3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

21 C.F.R. § 803.10.

44. The FDA explains the requirement to file adverse event reports as follows:

> ***Mandatory reporters (i.e., manufacturers***, device user facilities, and importers) ***are required to submit certain types of reports for adverse events and product problems to the FDA about medical devices***. In addition, the FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety.
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> ***Manufacturers: Manufacturers are required to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury. Manufacturers must also report to the FDA when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.***
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> *** * ***
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> **Device User Facilities**: A "device user facility" is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office. User facilities must report a suspected medical device-related death to both the FDA and the manufacturer. User facilities must report a medical device-related serious injury to the manufacturer, or to the FDA if the medical device manufacturer is unknown. [3]

45. Manufacturers must also report to the FDA, within 30 days, ***any "information***, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 CFR § 803.50. In connection with any such report, the

[3] U.S. FDA, *Medical Device Reporting (MDR)*, https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

manufacturer is "responsible for conducting an investigation of each event and evaluating the cause of the event" and for "obtaining and submitting to [the FDA] information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters." *Id*.

46. Manufacturers must also prepare and submit periodic reports to the FDA that, among other things, must contain "a summary and bibliography" of ***all "[u]published reports of data from any clinical investigations or nonclinical laboratory studies involving the device*** or related devices and known to or that reasonably should be known to the applicant" and ***all "[r]eports in the scientific literature concerning the device*** and known to or that reasonably should be known to the applicant." 21 C.F.R. § 814.84(b)(2)).

47. Manufacturers must also "establish and maintain procedures for receiving, reviewing, and evaluating complaints," which includes a requirement to "review[], evaluate[], and investigate[]" "[a]ny complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications" and "to determine whether the complaint represents an event which is required to be reported to FDA." 21 CFR § 820.198.

48. Since 1996, the FDA has made adverse event reports publicly available through an online database called Manufacturer and User Facility Device Experience ("MAUDE").[4] Today, MAUDE contains over 4 million medical-device adverse-event reports dating back to 1991, including voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. MAUDE is heavily cited and relied

[4] *See* U.S. FDA, *MAUDE — Manufacturer and User Facility Device Experience*, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

upon in the medical literature, and "medical experts trust [MAUDE] to identify problems that could put patients in jeopardy."

Breast Implants

49. There are three general types of breast-implant products, defined by their filler material: saline solution, silicone gel, and composite filler. Silicone gel-filled breast implants have a silicone outer shell and are filled with silicone gel. They are available in various sizes and can have either a smooth or textured shell.

50. Silicone gel-filled breast implants were introduced to the United States in 1962. After Congress passed the MDA in 1976, the FDA initially classified breast implants as Class II devices.

51. In the early 1980s, concerns arose about the safety of breast implants, in particular, silicone gel-filled breast implants. Tens of thousands of women blamed afflictions ranging from autoimmune disease to breast cancer on their silicone implants. The first report that silicone breast implants were potentially related to autoimmune disease surfaced in 1982 as a series of three case reports of patients who developed autoimmune connective tissue disease (Systemic Lupus Erythematosus, Mixed Connective Tissue Disease and Rheumatoid Arthritis) within three years of their cosmetic breast augmentation.[5] The increasing reports of an association of silicone with adjuvant disease led to the filing of multiple court actions against the leading implant manufacturer of the day, Dow Corning. Additionally, the FDA's new surveillance systems identified frequent local complications and adverse outcomes, and other published case reports described cancer and connective tissue disease in some women with breast implants.

[5] S.A. van Nunen, et al., *Post-mammoplasty connective tissue disease*, Arthritis Rheum. 1982; 25(6):694-97, https://www.ncbi.nlm.nih.gov/pubmed/7092967.

52. Thus, in 1982, under pressure from increasing reports of adverse events including capsular contracture, gel bleed, and possible link to autoimmune disease, the FDA decided to reclassify breast implants as Class III devices. Therefore, Allergan's breast implants are classified as Class III devices.

53. In 1991, following congressional hearings and popular opinion that implant companies were covering up evidence, the FDA issued a call for all manufacturers to submit safety and efficacy PMA data. When the safety and efficacy data were finally received and reviewed by the FDA, the FDA criticized all the studies as too small and too short-term to prove safety.

54. In January 1992, the FDA imposed a "voluntary moratorium" on breast implants. This required the suspension of all sales and implantation of devices, pending receipt of new safety data. Implants could only be used for breast reconstruction or those receiving replacement for an existing implant and only in the context of ongoing prospective clinical studies. Many patients were enrolled, but because the goal was to simply satisfy entry into a trial, patients quickly dropped out of the studies, which negatively affected long-term follow-up data.

Allergan Gets Conditional FDA Approval

55. In 1999, a panel of independent experts at the Institute of Medicine (since renamed the National Academies' Health and Medicine Division) published a review of existing studies of silicone breast implants. The panel concluded that although implants caused frequent local complications, more serious problems such as autoimmune disease, cancer and other systemic illnesses were "no more common in women with breast implants than in women without implants."

56. This promoted breast-implant manufacturers and plastic surgeons to lobby heavily in an effort to convince the FDA to restore silicone breast implants to the market. Manufacturers churned out studies supporting breast implant safety to back new applications for approval, and plastic surgeons and their patients testified to the FDA asserting their right to make choices about their own bodies.

57. For several years, they faced significant opposition, yet they were persistent. According to Susan Wood, director of the FDA's Office of Women's Health from 2000 to 2005, the manufacturers were so tenacious that "[t]hey just wore down any resistance."[6]

58. Doctors continued to have serious doubts about the long-term safety of silicone implants. For example, after an FDA advisory panel voted to restore silicone implants to the market in 2003, its chairman, Dr. Thomas Whalen, resigned in protest and urged the FDA to disregard the recommendation. In his resignation letter, Dr. Whalen wrote, "To approve this device poses threats to women that are clearly unknown…. Once this horse is out of the barn, indeed for a second time, there will be no recourse."[7]

59. Ultimately, the FDA overruled the advisory panel's decision to restore silicone implants to the market, but this prompted fierce continuation of the internal debate. Two years later the advisory panel reversed its decision and voted, 5 to 4, against restoring silicone implants.

60. However, in 2006 the FDA once again changed course. In November 2006, the FDA approved two silicone breast implants for sale on the U.S. market: Allergan's Natrelle

[6] Sasha Chavkin, *Breast Implant Injuries Kept Hidden As New Health Threats Surface*, ICIJ—The Implant Files (Nov. 26, 2018), https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface/

[7] *Id.*

implants, and Mentor Worldwide LLC's MemoryGel implants. However, the approvals were conditional: Allergan and Mentor were ordered to conduct six post-market safety studies, including device-failure studies, focus groups and physician surveys to assess the device labeling and long-term studies that would follow 40,000 women over 10 years.

61. Specifically, the six post-approval studies for Allergan's Natrelle Silicone-Filled breast implants included:

a. *Core Post-Approval Studies (Core Studies)* – To assess long-term clinical performance of breast implants in women that enrolled in studies to support premarket approval applications. These studies were designed to follow women for 10 years after initial implantation.

b. *Large Post-Approval Studies (Large Studies)* – To assess long-term outcomes and identify rare adverse events by enrolling more than 40,000 silicone gel-filled breast implant patients, following them for 10 years.

c. *Device Failure Studies (Failure Studies)* – To further characterize the modes and causes of failure of explanted devices over a 10-year period.

d. *Focus Group Studies* – To improve the format and content of the patient labeling.

e. *Annual Physician Informed Decision Survey (Informed Decision Study)* – To monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants.

f. *Adjunct Studies* – To provide performance and safety information about silicone gel-filled breast implants for the period when implants could only be used for reconstruction and replacement of existing implants.

62. The FDA's approval letter explicitly stated that "[f]ailure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA."

The Link between Breast Implants and ALCL Was Known Before the Class Period

63. ALCL is a rare type of non-Hodgkin lymphoma. ALCL is characterized by abnormal growth of T-lymphocytes (T-cells) and strong expression of a protein, cytokine receptor CD30. ALCL can involve many parts of the body, including the lymph nodes and skin. There are two major variants of ALCL recognized in the literature: ALK-positive, which expresses the protein anaplastic lymphoma kinase, and ALK-negative, which does not.[8]

64. Breast-Implant-Associated ALCL ("BIA-ALCL") was first reported in a 1997 study that described a case of ALK-negative ALCL in silicone and saline-filled breast implants.[9] BIA-ALCL garnered more attention after 2008, when a study described four patients with a CD30-positive T-cell lymphoproliferative disorder surrounding breast implants, which they designated as seroma-associated primary anaplastic large cell lymphoma.[10] As discussed further below, since that time, evidence has accumulated showing that BIA-ALCL is a unique clinicopathologic entity that requires unique management and therapeutic approaches and is under-recognized and under-reported.

65. In November 2008, JAMA published a study by a group of Dutch researchers that had identified 11 patients with breast implants and reported ALCL of the breast diagnosed

[8] *See generally* Lymphoma Research Foundation, http://www.lymphoma.org/site/pp.asp?c=bkLTKaOQLmK8E&b=6293639.

[9] J.A. Keech & B.J. Creech, *Anaplastic T-cell lymphoma proximity to a saline-filled breast implant*, Plast. Reconstr. Surg. 1997; 100(2):554-55.

[10] A.C. Roden, et al. *Seroma-associated primary anaplastic large-cell lymphoma adjacent to breast implants: an indolent T-cell lymphoproliferative disorder*, Mod. Pathol. 2008; 21:455-63.

between 1990 and 2006.[11] The study found a positive association between breast implants and the development of ALCL, with an odds ratio of 18:2—meaning that patients with implants were 18 times more likely to develop ALCL than patients without breast implants. The study concluded that "[b]ecause nodal-type ALCL is a very rare disease with a frequency in population-based studies of approximately 3%, the unusual distribution of this lymphoma type in case reports ***supports an association between ALCL and breast implants***."

66. In January 2011, the FDA issued a report titled "Anaplastic Large Cell Lymphoma (ALCL) In Women with Breast Implants."[12] The report stated that "in a thorough review of scientific literature published from January 1997 through May 2010, the FDA identified 34 unique cases of ALCL." The FDA concluded***, "The FDA believes that there is a possible association between breast implants and ALCL."*** The FDA further noted that while it was not prepared to associate a particular type of breast implant with ALCL, "ALCL has been found ***more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell."***

67. In February 2011, the United Kingdom's Medical and Health Products Regulatory Agency ("MHRA") issued a medical device alert, stating, "[t]here is uncertain evidence that ***women with breast implants may have a small but increased risk of anaplastic cell lymphoma***

[11] D. de Jong, W.L. Vasmel, J.P. de Boer, et al., *Anaplastic large-cell lymphoma in women with breast implants*, JAMA, 2008, 300(17): 2030-35.

[12] U.S. FDA, *Anaplastic Large Cell Lymphoma (ALCL) In Women with Breast Implants: Preliminary FDA Findings and Analyses* (Jan. 2011), *available at* http://wayback.archiveit.org/7993/20171115053750/https:/www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm.]

(ALCL) of the breast" and encouraging "all surgeons to report all adverse incidents including cases of ALCL."[13]

68. Despite the FDA's January 2011 Report, a spokeswoman for Allergan, whose products, along with Johnson & Johnson's, were linked to the cases, downplayed the concerns in an emailed statement: "***A woman is more likely to be struck by lightning than get this condition***," said Caroline Van Hove. "Patients' safety is Allergan's absolute first priority and ***we continue all efforts to collect and analyze further information about the very rare occurrence of ALCL in patients with breast implants***."[14]

69. In August 2012, the American Society of Plastic Surgeons ("ASPS"), the Plastic Surgery Foundation ("PSF") and the FDA signed a cooperative research and development agreement to develop an infrastructure where all past and future cases of breast implant-associated ALCL could be centralized. This collaboration resulted in a patient registry titled, "Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology" ("PROFILE"). This registry is available to implant manufacturers who could access the registry and were able to track the incidence of BIA-ALCL.

70. In 2012, the first cases of ALCL in women with breast implants began to be reported in Australia. Allergan products are linked to the highest numbers of BIA-ALCL cases in Australia. This prompted the Company to publish a study, in May 2012, with the goal of

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[13] U.K. MHRA, *Medical Device Alert: All types, makes and models of breast implants* (Feb. 16, 2011), MDA/2011/017, https://www.gov.uk/drug-device-alerts/medical-device-alert-all-types-makes-and-models-of-breast-implants-potential-increased-risk-of-anaplastic-large-cell-lymphoma-alcl.

[14] Kim LaCapria, *FDA: Breast implants may be linked to rare cancer,* Inquisitr (Jan. 26, 2011), https://www.inquisitr.com/96723/breast-implants-cancer-risk/.

counteracting the negative press surrounding the alarming incidence of BIA-ALCL linked to Allergan implants.

71. The Allergan-sponsored study estimated the incidence of developing BIA-ALCL at 1.46 for every 100,000 breast implants.[15]

72. Professor Anand Deva, Director of Cosmetic and Plastic Surgery at the Australian School of Advanced Medicine, described the Allergan-sponsored study as using "crude figures" and as looking at "broad risk and there's a lot of flaws in doing that."[16] He further noted that the study played down the risk to patients and effectively served to silence debate among academics and regulators on the emerging issue. An ABC News analysis confirmed that in the years after the 2012 Allergan-sponsored study was published, case reports stagnated and warnings from regulators about the illness were not as frequently updated. The study has also been criticized as inadequate, due to the short period of observation – at 2.7 years, when considering that the median time from implantation to diagnosis of BIA-ALCL is 9 years.

73. In 2014, more information linking breast implants to the development of ALCL continued to emerge. For example, in May 2014 the final report on poly implant prothèse ("PIP") silicone breast implants was published by the European Commission and its non-food Scientific Committee on Emerging and Newly Identified Health Risks ("SCENIHR"), which identified 130 case reports worldwide of patients with all types of breast implants who had developed ALCL. Also, in July 2014, the MHRA issued a Medical Device Alert "to further encourage healthcare

[15] J. Largent, et al., *Risk of lymphoma in women with breast implants: analysis of clinical studies*, European Journal of Cancer Prevention, May 2012, 21(3):274-80.

[16] Alison Branley, Mario Christodoulou, Sophie Scott & Alex Mann, *The Implant Files reveal how breast implants linked to rare cancer set off alarm bells*, Aus. Broadcasting Corp. (Nov. 27, 2018, 8:41PM), https://www.abc.net.au/news/2018-11-27/implant-files-breast-implants-probe-exposes-tga-flaws/10496080.

professionals to report cases of ALCL in women who have breast implants or who have had them removed."[17]

74. According to CW1, sometime during the last year of CW1's employment, 2013-2014, the Company began working on changes to the textured breast implants which involved changing the texture as well as a manufacturing technique or cleaning of the implant. While CW1 was not told by the Company that these suggested changes were related to the link between textured implants and the development of ALCL, it was shortly thereafter that studies began to be published alerting to this precise link.

75. For example, in March 2015 (published online on December 8, 2014) a major analysis of the breast implant and ALCL connection was published, which identified 173 cases of BIA-ALCL.[18] The authors reviewed 37 articles in the world literature reporting on 79 patients and collected another 94 unreported cases. The study confirmed that there are no known pure smooth implant cases. ***Additionally, the study determined that out of 170 breast implants, in 61 cases the manufacturer was unknown yet in 97 cases (or 56%) the implants were Biocell Allergan/Inamed/McGhan. By far, the largest percentage of implants with associated breast-implant ALCL were manufactured by Allergan/Inamed/McGhan.***

[17] U.K. MHRA, *Medical Device Alert: Breast implants. All types, makes and models* (Jul. 10, 2014), MDA/2014/027, https://www.gov.uk/drug-device-alerts/medical-device-alert-breast-implants-report-cases-of-anaplastic-large-cell-lymphoma-alcl.

[18] G.S. Brody, et al. *Anaplastic large cell lymphoma occurring in women with breast implants: analysis of 173 cases*, Plast. Reconstr. Surg., Mar. 2015; 135(3):695-705, https://www.ncbi.nlm.nih.gov/pubmed/25490535.

76. Another article, also published in March 2015, stated that "***there is substantial evidence that a type of anaplastic large cell lymphoma (ALCL) is associated with breast implants.***"[19]

77. Also, in March 2015, the French National Cancer Institute (Agence Nationale de Sécurité du Médicament, "ANSM") announced, "***There is a clearly established link between the occurrence of this disease and the presence of a breast implant***."

78. Allergan was well-aware of the studies that had determined a higher incidence of BIA-ALCL in patients with the Company's implants. For example, in July 2015 Drs. Mollie Carter and Joseph Purpora, employees of Allergan, submitted a letter to the editor of the Plastic Reconstructive Surgery Journal, commenting on the March 2015 study and article. The letter stated, "We read with great interest [the articles] and the associated discussions for both articles. We commend Dr. Brody on publishing his data, as we fully support transparent data sharing in the effort to better understand this rare condition. ***Allergan remains interested in elucidating the cause, diagnosis, and treatment of breast implant–associated anaplastic large cell lymphoma and is committed to supporting this important research***."

79. In 2016, more information continued to come out addressing the link between breast implants and ALCL as regulatory agencies around the world began making more definitive and stronger statements alerting of the link.[20] For example, in May 19, 2016, the

[19] C.A. Gidengil, et al., *Breast implant–associated anaplastic large cell lymphoma: A systematic review*, Plast. Reconstr. Surg., Mar. 2015; 135(3):713–20, https://www.ncbi.nlm.nih.gov/pubmed/25490539.

[20] Steven H. Swerdlow, et al., *The 2016 revision of the World Health Organization classification of lymphoid neoplasms*, Blood (2016), 127(20), 2375-90, http://www.bloodjournal.org/content/127/20/2375.

World Health Organization ("WHO") issued a guidance definitively linking breast implants to ALCL and officially named the disease "breast implant associated ALCL."

80. In July 2016, the ANSM released an update stating that, based upon 29 cases of ALCL reported, and due to the predominance of textured cases, it was calling for all implant manufacturers selling in France to submit clear data for textured implants within the year or their respective devices would be restricted from sale.[21]

81. In November 2016, Australia's Therapeutic Goods Administration ("TGA") convened an expert advisory panel to discuss the association between breast implants and ALCL and to provide ongoing advice. In December 2016, the TGA issued a report about ALCL which indicated a substantially higher risk associated with textured versus smooth implants. Furthermore, the TGA-reported incidence rate was in the range of 1:1,000-10,000 for patients with textured implants.[22]

More Information about ALCL Continues to Emerge during the Class Period

82. By January 2017, Allergan was aware that there were grave concerns about their breast implants and the development of BIA-ALCL.

The January 30, 2017 *ABC News 7 on Your Side* article

83. A January 30, 2017 *ABC News 7 on Your Side* article described two women who received Allergan textured implants and participated in Allergan post-approval studies for two

[21] Mark W. Clemens, et al., *Understanding rare adverse sequelae of breast implants: anaplastic large-cell lymphoma, late seromas, and double capsules*, Gland Surgery Vol. 6,2 (2017): 169-84, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5409903/.

[22] Aus. Dept. Health, Therapeutic Goods Admin., *Breast implants and anaplastic large cell lymphoma*, Dec. 20, 2016, https://www.tga.gov.au/alert/breast-implants-and-anaplastic-large-cell-lymphoma.

years before they were told that the studies—which were "supposed to span 10 years"— had been dropped.[23] *ABC News 7* asked Allergan to respond and explain why their post-approval study was terminated. Defendant DeSena stated:

> Upon receiving approval for the Natrelle 410 breast implant, Allergan was required to conduct post-approval follow-up studies of approximately 3,500 patients who were enrolled in the 410 clinical study. These studies were part of the normal FDA approval process for breast implants and were not specific to BIA-ALCL. ***Allergan fulfilled all of its post-approval commitments in 2014 and requested FDA's approval to discontinue the studies early in light of Allergan meeting all post-approval commitments.*** FDA approved Allergan's request and the studies were discontinued in 2014. The discontinuation of these post-approval studies had nothing to do with BIA-ALCL. Allergan complied with standard protocols and regulations relating to the termination of the studies, which included proper notification to the trial sites and the Institutional Review Boards.
>
> The link to the FDA website provided below is to a Natrelle 410 case-control study that Allergan never conducted because FDA ultimately deemed it unnecessary. The case-control study was designed to evaluate several rare diseases, including rare CTDs, rare neurological diseases, brain cancer, cervical/vulvar cancer, and lymphoma.
>
> Lastly, to reiterate, Allergan has a robust post-market surveillance process (e.g., collecting reports of BIA-ALCL from surgeons, notifying FDA and other international regulatory agencies of all suspected cases, monitoring literature and case presentations, etc.) to monitor and report suspected cases of BIA-ALCL.

84. Defendant Marmur also submitted the following written statement:

> Patient safety is always Allergan's first priority. However rare, Allergan takes this disease seriously.

[23] Kimberly Suiters, *Woman who beat cancer once says breast implants caused cancer again*, ABC7 (Jan. 30, 2017), https://wjla.com/features/7-on-your-side/woman-who-beat-breast-cancer-once-says-breast-implants-caused-cancer-again.

According to the FDA, BIA-ALCL has been reported in patients with textured breast implants from all manufacturers. Because of the limited number of confirmed BIA-ALCL case worldwide, the medical community has not been able to establish causality.

Allergan is actively working to help advance the knowledge of this disease, understand the association of BIA-ALCL and textured implants, and educate the community, including:

- Working closely with the FDA and global regulatory bodies to ensure that our products' labeling documents include all information necessary for healthcare professionals and patients. This includes safety data, precautions, warnings, potential side effects. In addition, Allergan has added information on BIA-ALCL as a rare adverse event into the patient literature that accompanies every pack of implants in the US and internationally.

- Convening global medical experts and researchers to foster collaboration and advance the medical community's knowledge and awareness of the disease. Allergan also has conducted surgeon education meetings and webcasts in the US and internationally since 2014.

- Working closely with FDA and other regulatory authorities to submit all reports of BIA-ALCL annually. Please see the FDA's web site for additional information: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm240000.htm#howtoreport;

- Supporting ongoing research to ensure physicians and patients have the latest scientific findings to appropriately diagnose and effectively treat the disease, ensuring women are appropriately informed, monitored, and managed if diagnosed with BIA-ALC.

- Partnering with ASPS, ASAPS and ISAPS to distribute BIA-ALCL educational materials and work with these societies on guidance for healthcare professionals regarding the appropriate management of patients.

85. *ABC News 7* responded by submitting the following questions to Allergan:

- To the extent that it is possible, will Allergan track down, or ask surgeons to track down, every woman who received textured breast implants to inform them of the small but potential risk of BIA-ALCL?

- What is Allergan's plan moving forward to help educate women and physicians about the issues regarding textured breast implants and ALCL? If an information campaign is in the works, please share the details;

- Is Allergan currently researching possible causation between textured breast implants and ALCL? When will results be released (whether to the FDA, ANSM, or the public at large)?

- Do you consider ALCL to be exclusive to the textured implants? If yes, what is it about texturing that appears to be problematic?

- How many cases of ALCL did you discover prior to adding it to your label, and when was it added?

86. DeSena replied by email with responses only to what appear to be questions one and five:

> 1) To the extent that it is possible, will Allergan track down, or ask surgeons to track down, every woman who received textured breast implants to inform them of the small but potential risk of BIA-ALCL?
>
> ***Allergan continues to provide educational information regarding this disease to both physicians and patients, as well as working with the FDA and regulatory authorities to collect and assess safety reports*** to help inform the physician community, regulatory agencies and patients on the appropriate use of our implants. The surgeon and patient FDA-approved labeling for Allergan's breast implants – as well as the labeling documents of all other breast implant manufacturers – discusses BIA-ALCL. Both the FDA and the leading plastic surgeon societies (ASPS and ASAPs) encourage routine breast care and support for patients who have received breast implants…
>
> 6) How many cases of ALCL did you discover prior to adding it to your label, and when was it added?

> Manufacturers have been reporting cases of BIA-ALCL as they have occurred, leading to FDA's press release in 2011 informing the public of the potential association between breast implants and the development of ALCL. Then, US breast implant manufactures worked with FDA to develop language to be included in approved labeling documents, which were released in 2013. ***Allergan complies with applicable regulations relating to the reporting of BIA-ALCL to the FDA***. The FDA has a webpage devoted to reports of ALCL it receives from breast implant manufacturers, which includes the date range of the reports, information regarding the type of implants, whether the surgery was for reconstruction or augmentation, etc.

The January 2017 Study

87. In January 2017 (published online on December 28, 2016), Allergan sponsored a study purported to examine the incidence of capsular contracture, malposition and late seroma in patients that received the Company's Natrelle 410 breast implant.[24] The study pulled data from two ongoing, prospective, multicenter 10-year studies of 17,656 patients that received the implant. While the study did not examine, nor was it focused on determining the incidence of BIA-ALCL, the authors noted that, "Interest in late seroma [a complication that manifests as fluid collection in the periprosthetic space] has increased because of its similar clinical presentation compared with breast implant–associated anaplastic large cell lymphoma. Most cases of late seroma have been observed in subjects receiving textured implants." ***The study found that out of the 17,656 patients, four developed ALCL. This would in fact suggest an incidence rate, at the time of the study, of close to one per 4,000 Natrelle 410 implants implanted.*** Nevertheless, the study found that the incidence of capsular contracture, implant

[24] Patricia McGuire, et al., *Risk Factor Analysis for Capsular Contracture, Malposition, and Late Seroma in Subjects Receiving Natrelle 410 Form-Stable Silicone Breast Implants,* Plastic and Reconstructive Surgery Vol. 139,1 (2016): 1-9, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5201411/.

malposition and late seroma were low enough to conclude that, ***"[t]hese data reaffirm the safety of the Natrelle 410 breast implant."***

The March 2017 FDA Update

88. In March 21, 2017, the FDA released a safety communication updating its January 2011 report and the current understanding of ALCL.[25] The FDA stated,

> In 2011, the FDA identified a possible association between breast implants and the development of anaplastic large cell lymphoma (ALCL).
>
> At that time, the FDA knew of so few cases of ALCL that it was not possible to determine what factors increased a patient's risk. In a report summarizing the Agency's findings, we emphasized the need to gather additional information to better characterize ALCL in individuals (cis- and trans-gender women and men) with breast implants.
>
> Over time, we have strengthened our understanding of this condition. In 2016, the World Health Organization designated breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as a T-cell lymphoma that can develop following breast implants. The exact number of cases remains difficult to determine due to significant limitations in world-wide reporting and lack of global breast implant sales data. ***At this time, most data suggest that BIA-ALCL occurs following implantation of breast implants with textured surfaces rather than those with smooth surfaces.***

89. The FDA March 2017 update produced the expected press coverage as well as new studies focused on the link between breast implants and ALCL. For example, a March 22, 2017, *Forbes* article[26] noted that the FDA had received nine reports of women dying from ALCL after

[25] U.S. FDA, *Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)*, Mar. 21, 2017, https://web.archive.org/web/20170322204822/https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm.

[26] Rita Rubin, *FDA Agrees With WHO, Links Breast Implants To Rare Cancer? How Worried Should Women Be?*, Forbes (Mar. 22, 2017), https://www.forbes.com/sites/ritarubin/2017/03/22/fda-agrees-with-who-links-breast-implants-to-rare-cancer-how-worried-should-women-be/.

getting breast implants and also reported that, "As of Feb 1, the FDA says, it had received a total of 359 reports of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)." The article also noted that the FDA reported that out of the 231 reported cases of ALCL that contained information about the implant's surface, 203 were reported to be textured implants.

90. The March 22, 2017 article quoted Dr. Roberto Miranda, a pathologist at M.D. Anderson Cancer Center in Houston and one of the top experts on the disease, stating that possible explanations for why textured implants appear to carry a higher risk of ALCL may be because the thin layer of bacteria, called a biofilm, that forms on the surface of textured implants could trigger a response by the immune system that leads to ALCL.

Medical Studies Continue to Affirm the Higher Risk of BIA-ALCL

91. In April 2017, Dr. Miranda and Dr. Mark W. Clemens, a plastic surgeon and expert on ALCL also from the M.D. Anderson Cancer Center in Houston, published an article.[27] They performed a literature review on the etiology and sequelae of ALCL and confirmed that "***textured implants are commonly implicated in the development***" of ALCL. Additionally, the study pulled data from the MD Anderson's ALCL Tracking Reporting (worldwide), the University of Southern California's ("USC") ALCL Tracking Reporting (worldwide) and the FDA's Manufacturer and User Facility Device Experience ("MAUDE") – an FDA database that houses medical device reports submitted to the FDA by mandatory reporters which includes implant device manufacturers – to determine the distribution of breast implant-associated ALCL by manufacturer. The data showed that out of the worldwide cases reported to MD Anderson

[27] M.W. Clemens, et al., *Understanding rare adverse sequelae of breast implants: anaplastic large-cell lymphoma, late seromas, and double capsules,* Gland. Surg. Apr. 2017; 6(2):169-84, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5409903/.

Tracking 2016, ***76 (or 41.8%) of the ALCL cases reported were Allergan/Inamed/McGhan implants***. The data showed that out of the worldwide cases reported to USC 2015, ***97 (or 56%) of the ALCL cases reported were Allergan/Inamed/McGhan implants.*** Finally, the data showed that out of the US cases reported to the FDA MAUDE database, ***184 (or 80.3%) of the ALCL cases reported were Allergan/Inamed/McGhan implants***. These are shockingly large percentages associated with Allergan/Inamed/McGhan implants.

92. In May 2017, Drs. Miranda and Clemens, along with other colleagues, published another study to determine the U.S. incidence and lifetime prevalence of BIA-ALCL in women with textured breast implants.[28] The study entailed a review of documented cases of BIA-ALCL in the U.S. from 1995 to 2015 and identified one hundred pathologically confirmed cases. The study determined that the lifetime prevalence of the disease was 1 out of 30,000 women with textured breast implants. The study also found that 43 percent of patients with BIA-ALCL had a salt-loss implant, the type manufactured by Allergan, while only 5 percent had a negative-imprint stamping technique implant. The study concludes, "This is the first U.S. report demonstrating that the absolute risk of developing breast implant-associated ALCL around a textured breast implant appears to be significantly higher than the risk of developing primary breast ALCL in the general population…***the study finds the incidence to be approximately 66 times higher than that of primary breast ALCL in the general population."***

[28] E.L. Doren, R.N. Miranda, J.C. Selber, et al., *U.S. epidemiology of breast-implant–associated anaplastic large cell lymphoma*, Plast. Reconstr. Surg. 2017;139:1042–50, https://www.ncbi.nlm.nih.gov/pubmed/28157769.

93. On May 14, 2017, *The New York Times* published an article titled, "A Shocking Diagnosis: Breast Implants 'Gave Me Cancer."[29] The article reported that in 2011, after the FDA first reported a link between breast implants and ALCL, information was added to the products' labeling. However, the warnings are deeply embedded in a dense list of complications.

94. The May 14, 2017 article also stated that currently researchers estimate that in Europe and the United States, 1 in 30,000 women with textured implants will develop the disease. But in Australia the estimate is higher: 1 in 10,000 to 1 in 1,000. Dr. Clemens stated that Allergan implants seem to be associated with more cases than other types, likely because they are more deeply textured and have more surface area for bacteria to stick to. An Allergan spokesman, responding for comment in an email, stated, "***Allergan is studying bacterial biofilms, and immune and inflammatory responses to breast implants***." He added that ***the company took the disease seriously and was working with professional societies to distribute educational materials about it***. The article also stated that, "[w]omen who have had the lymphoma say that the attention is long overdue, that too few women have been informed of the risk and that those with symptoms often face delays and mistakes in diagnosis, and difficulties in receiving proper care. Some have become severely ill." One of the women quoted in the article is Ms. Kimra Rogers, a nursing assistant from Idaho who learned in May 2016 that she had developed lymphoma from Allergan textured implants. Ms. Rogers sued Allergan in May 2018.

[29] Denise Grady, *A Shocking Diagnosis: Breast Implants 'Gave Me Cancer'*, N.Y. Times (May 14, 2017), https://www.nytimes.com/2017/05/14/health/breast-implants-cancer.html.

Allergan Kept Track of BIA-ALCL and Knew of the Increase in Reports of BIA-ALCL Linked to its Breast Implants

95. According to CW2, despite the growing number of studies and concerns regarding the link between textured implants and ALCL, the Company never asked its breast implant research team to conduct any studies into claims that the implants were causing breast implant-associated ALCL. CW2 added, "***We did not study ALCL***. We did know about it…. We only knew what was published in the papers." When asked why Allergan did not conduct research into ALCL, CW2 stated, "We didn't want to even go there with ALCL." When asked why the Company "did not want to go there," CW2 stated, "I don't really have a good answer for that."

96. CW2 as well as CW2's colleagues were well-aware of the reports about the possible link. CW2 said that they heard about it from published research papers, media reports and presentations at medical conferences. According to CW2, Allergan sent researchers and management to a number of conferences for breast implant surgeons, including the ASPS. CW2 recalled that research studies on the possible link between breast implants and ALCL were presented at a number of conferences that Allergan employees attended. Employees that attended the conferences usually discussed the topic with employees who did not attend. According to CW2, Allergan sent Vice Presidents to the conferences as well as lower level employees.

97. CW2 explained that even though Allergan was well-aware of the link, not only did the Company never asked CW2's breast implant research team to conduct any research into the link, but in 2014, just prior to its acquisition by Activis, the Company shut down its Santa Barbara facility, which was the center of breast implant research and development. The Company also laid off most of the breast implant research team. Allergan kept only five of the 30 team members and transferred them to the Company's facilities in Irvine, CA.

Evidence of Heightened Risk Continues to Build

98. On July 19, 2017, *The Independent* published an article stating that "[e]xperts have called for a common type of breast implant [textured] to be banned after it was revealed two people died and 23 developed the same type of cancer in the UK following breast enlargement surgery."[30] The article quoted cosmetic surgery expert Professor James Frame, as calling the disease a "potential bombshell that has been swept under the carpet for five years."

99. In September 13, 2017, the TGA issued an update stating that it had confirmed more cases of breast implant-associated ALCL, with a total of 56 cases reported to-date.[31] A September 30, 2017 update from the FDA reported that the FDA had received a total of 414 medical device reports related to breast implants and ALCL which included nine deaths.

100. In October 2017, an explosive study was released by a large group of researchers, which included Allergan and Mentor research coordinators and consultants, that definitively found that Allergan's deeply textured implants ***significantly increased the risk of developing ALCL*** in Australia and New Zealand.[32] The study identified and analyzed all cases of breast implant-associated ALCL in Australia and New Zealand – 55 cases diagnosed between 2007 and

[30] Katie Forster, *Calls to ban textured breast implants after two die and 23 develop same type of cancer*, Independent.co.uk (Jul. 10, 2017, 08:58 AM), https://www.independent.co.uk/news/health/breast-implants-cancer-ban-two-die-23-develop-same-type-textured-common-women-enlargement-cosmetic-a7832996.html.

[31] Aus. Dept. Health, Therapeutic Goods Admin., *Breast implants and anaplastic large cell lymphoma*, Sept. 13, 2017, https://www.tga.gov.au/alert/breast-implants-and-anaplastic-large-cell-lymphoma.

[32] A. Loch-Wilkinson, et al., *Breast Implant-Associated Anaplastic Large Cell Lymphoma in Australia and New Zealand: High-Surface-Area Textured Implants Are Associated with Increased Risk*, Plast. Reconstr. Surg., Oct. 2017; 140(4):645-54, https://www.ncbi.nlm.nih.gov/pubmed/28481803.

2016 and 75 devices were employed. The task force also engaged the three major implant manufacturers in the Australia and New Zealand market – Allergan, Mentor and Silimed – to release sales data for implants between 1999 and 2015.

101. The researchers performed surface area analysis to confirm that higher surface area was associated with 64 of the 75 implants used (85.3%). Furthermore, ***Biocell salt textured implants (Allergan, Inamed and McGhan) accounted for 58.7% (44) of the implants used***. Comparative analysis showed that the risk of developing breast implant-associated ALCL was ***14.11 times higher for Biocell as compared to Mentor's Siltex textured implant.*** There were four reported patient deaths – all four had Biocell implants. The study also found that, ***"[t]he highest estimated risk as expressed as cases of ALCL per number of implantation was found for Biocell texture at one in 3817."***

102. On October 18, 2017, JAMA Surgery published a report which consisted of a literature review of all BIA-ALCL articles conducted in an academic medical setting. Based on this review, the researchers determined that they "expect[ed] to see a rise in the number of cases of BIA-ALCL diagnosed."[33]

103. On January 4, 2018 the same group of Dutch researchers that in 2008 performed the first relative risk estimate for breast implant-associated ALCL looking at reported cases in the Netherlands, updated their epidemiological study covering cases in the 1990 to 2016 period.[34] ***The study reported the risk of developing ALCL to be 421.8 x higher in women with***

[33] A. Leberfinger, et al., *Breast Implant-Associated Anaplastic Large Cell Lymphoma – A Systemic Review*, JAMA Surgery Review, Oct. 2017; 152(12):1161-68, https://www.ncbi.nlm.nih.gov/pubmed/29049466.

[34] M. de Boer, et al., *Breast Implants and the Risk of Anaplastic Large-Cell Lymphoma in the Breast*, JAMA Oncol., Jan. 2018; 4(3):335-41, https://www.ncbi.nlm.nih.gov/pubmed/29302687.

breast implants than with women with no implants, "implying an attributable risk approaching 100%...." Further confirming the increased risk associated with highly textured breast implants, the study found that of the 28 patients with ALCL with known implant type, 23 (82%) had macrotextured implants – of the 23, 22 patients were implanted with Allergan/Inamed/McGhan implants.

104. In March 2018, the FDA issued an update which reported a total of 414 received reports of breast implant-associated ALCL – up from 359 a year earlier. The FDA further added that while the number of deaths it had recorded, nine, had not changed from a year ago, the ASPA was reporting 16 related deaths. The report also stated that the lifetime risk for breast implant-associated ALCL is between 1 in 3,817 and 1 in 30,000 women with textured breast implants.

105. On March 21, 2018, *The New York Times* published an article that reported that Defendant Marmur said by email that the Company was paying for research by outside investigators into causes of the lymphoma, working with plastic surgery societies on improved surgical techniques, adding information about the disease to its labeling and website, and giving surgeons educational materials for patients.[35] He also said that on January 1, 2018, Allergan changed the warranty on its textured implant to cover treatment for Allergan patients who received a diagnosis of the implant-associated lymphoma on or after that date, regardless of the implantation date.

[35] Denise Grady, *More Cases Are Reported of Unusual Cancer Linked to Breast Implants*, N.Y. Times (Mar. 21, 2018), https://www.nytimes.com/2018/03/21/health/breast-implants-lymphoma.html.

106. In May 9, 2018, the TGA issued an update stating that it had confirmed more cases of breast implant-associated ALCL, with a total of 72 cases reported.[36]

107. On May 29, 2018, Allergan issued a press release, "Allergan Responds to Media Reports on Breast Implant Associated Anaplastic Cell Lymphoma (BIA-ALCL)," defending its decision to market the controversial textured implants:

> Allergan manufactures a broad portfolio of breast implants, including those with textured and smooth surfaces. ***To date, we are not aware of any BIA-ALCL cases that have been found with other Allergan implants in Australia and New Zealand that do not include Biocell***…
>
> ***The safety profile of Allergan's smooth and textured breast implants is supported by extensive pre-clinical device testing, more than a decade of U.S. and European clinical experience involving more than 160,000 women[2], as well as a large number of peer-reviewed and published studies.[2]***
>
> ***
>
> When diagnosed and treated early by a surgical specialist, BIA-ALCL has a good prognosis.[7,8] Worldwide, ***BIA-ALCL has been reported with multiple different implant manufacturers.[9-13] Direct causality has not been established with implants from a specific manufacturer***.

108. In July 26, 2018, the MHRA issued another Medical Device Alert[37], stating,

> Since publishing MDAs in 2011 and 2014, encouraging healthcare professionals to report cases of anaplastic large cell lymphoma (ALCL) in patients with breast implants, ***MHRA has received 48 reports of BIA-***

[36] Aus. Dept. Health, Therapeutic Goods Admin., *Breast implants and anaplastic large cell lymphoma*, May 9, 2018, https://www.tga.gov.au/alert/breast-implants-and-anaplastic-large-cell-lymphoma.

[37] U.K. MHRA, *Medical Device Alert: Breast implants, all types, makes and models – Continue to report suspected cases of Breast Implant Associated - Anaplastic Large Cell Lymphoma* (Jul. 26, 2018), MDA/2018/027, https://www.gov.uk/drug-device-alerts/breast-implants-all-types-makes-and-models-continue-to-report-suspected-cases-of-breast-implant-associated-anaplastic-large-cell-lymphoma-mda-2018-027.

> ***ALCL in the UK***, 40 of which meet the WHO diagnostic criteria. There have also been more cases reported worldwide since publication of the WHO definition. In the UK, ***the estimated risk of BIA-ALCL, based on the reported confirmed cases is 1 per 28,000 implants sold***. This estimate is based on data for all types of breast implants known to be sold in the UK and reported cases of BIA-ALCL confirmed to meet the WHO criteria until December 2017. This is an estimate as some cases may not have been reported to the manufacturer or to MHRA during this period, additionally, all devices known to be sold in the UK may not have been implanted.

109. In August 2018, the FDA reported that as of Sept. 30, 2017, it had received 414 reports of the ALCL related to breast implants, including nine cases that were fatal. Of the 272 cases for which the implant surface was known, approximately 89% were textured. The FDA further noted that the real number of cases and size of the risk was not known, because there was a lack of information about how many women in the United States and worldwide had received implants. According to the FDA's best estimate, ALCL may occur in one in 3,817 to 30,000 women with textured implants.

110. On August 3, 2018, the *Philadelphia Inquirer* published an article that quoted Dr. Clemens as stating that ***for women who chose certain types of highly textured implants, the risk after a decade of wearing the devices could be as great as 1 in 2,200.*** [38] Dr. Clemens' estimate was extrapolated from Allergan's own two studies of its Natrelle 410 textured implants, published on January 2017, as discussed above. At the time the study was published, four women out of 17,656 had developed ALCL, which put the rate of incidence at close to 1 out of 4,000. By August 2018, eight women of the 17,656 had developed ALCL which increased the incidence to

[38] Marie McCullough, *As rough-surface breast implants cause more lymphoma cases, critics decry continued use*, Phila. Inquirer (Aug. 3, 2018), https://www.philly.com/philly/health/textured-breast-implants-cause-anaplastic-large-cell-lymphoma-critics-decry-continued-use-20180803.html.

1 out of 2,200. Dr. David A. Hidalgo, a prominent New York City plastic surgeon and professor at Weill Cornell Medical College, stated, "No one can prove any benefits to texturing…. If you remove the products, the risk goes to zero. To me, it's a no-brainer. Personally, I think they shouldn't be on the market." Dr. Eric Swanson, a plastic surgeon in suburban Kansas City, Kansas, added, "Even a remote risk is ethically indefensible if that risk is entirely unnecessary." Asked to respond, the FDA and the three manufacturing companies – Allergan, Mentor, and Sientra – said in statements that they are supporting lymphoma research, education, and initiatives to better understand the disease and increase awareness.

111. In August 28, 2018, Allergan sponsored a study to examine the tissue response associated with twelve different types of implants by different manufacturers including Allergan's Biocell textured implant.[39] While there was no mention of lymphoma throughout the study, the researchers acknowledged that implant surface texture does play a role in host tissue response and that increasing complexity of the surface texture of implants led to more tissue ingrowth. One of the leading theories on what causes the development of ALCL in women with textured implants is precisely that the texture contributes to higher biofilm load accumulation which could in turn lead to an immune reaction.

112. Two studies published online in September 2018 found more evidence linking textured breast implants to the development of ALCL and finding that silicone breast implants are associated with rare diseases. In a study published on September 11, 2018, researchers found that "with [] growing epidemiological data as well as strong clinical and pathological evidence, there is apparent substantial support for a pathogenic relationship" between breast implants and

[39] M. Atlan, et al., *Breast implant surface texture impacts host tissue response*, J. Mech. Behav. Biomed Mater., 2018;88:377-85, https://www.sciencedirect.com/science/article/pii/S1751616118307513.

the development of ALCL.[40] The study also concluded, "Overall, these data suggest that textured breast implants are more likely to be associated with subsequent breast implant ALCL." In a study published on September 13, 2018, which was the largest study of long-term safety outcomes for patients with breast implants, researchers at the MD Anderson Cancer Center, found that silicone implants are associated with some rare diseases, autoimmune disorders and other conditions.[41] The study analyzed data from the FDA's large post-approval studies (LPAS) which prospectively monitored long-term implant-related outcomes and systemic harm for silicone/saline implants from Allergan and Mentor. Allergan enrolled a total of 56,988 patients.

113. In September 2018, the PSF, in collaboration with the FDA and breast implant manufacturers – Allergan, Mentor and Sientra, launched the National Breast Implant Registry ("NBIR") for the stated purpose of strengthening national surveillance for breast implant devices in the United States. The NBIR is a database that collects information on breast implant procedures and devices.

114. A study published online on October 1, 2018 reported that due to their increased surface area, heavily textured implants allows the accumulation of a higher biofilm load than implants with smooth surfaces or less dramatic texturing.[42] The study compared biofilm formation on the outer surface for five different types of implants from three different manufacturers, including Allergan. Allergan's Biocell implant had statistically significantly more

[40] A.E. Quesada, et al., *Breast implant-associated anaplastic large cell lymphoma: a review,* Mod. Pathol., 2018, https://www.ncbi.nlm.nih.gov/pubmed/30206414.

[41] C.J. Coroneos, et al., *US FDA Breast Implant Postapproval Studies Long-term Outcomes in 99,993 Patients*, Annals of Surgery, Vol. 269, No. 1, Jan. 2019, https://www.ncbi.nlm.nih.gov/pubmed/30222598.

[42] G.A. James, et al., *Bacterial Adhesion and Biofilm Formation on Textured Breast Implant Shell Material*, Aesth. Plast. Surg., 2018, https://www.ncbi.nlm.nih.gov/pubmed/30276456.

bacterial attachment and biofilm formation than tested smooth surface implants. Interestingly, the disclosure section of the study stated, "In the past, these authors have performed similar testing services for Allergan, Inc."

115. On November 26, 2018, ABC News published an article titled, "Doctors, patients raise alarms about cancel linked to breast implants." The article reported that the FDA had more than 400 reports about patients who developed ALCL. The article also reported that the FDA would be holding public hearings on the issue in 2019 to try to find out more about the potential links between breast implants and ALCL and that France's ANSM would be doing the same and had, in the meantime, recommended against the use of textured implants.

116. The article further reported that makers of the breast implants had no immediate plans to stop selling textured versions. Allergan made the following statements:

> As with any medical procedure or device, patients considering breast implants are encouraged to have a comprehensive conversation with their surgeon about all potential risks and benefits, allowing for a fully informed decision,
>
> Based on available scientific information, global health agencies and manufacturers are not recommending any change in implant availability, current practice, post-implant care and check-ups,
>
> ***Allergan is and has been fully committed to investing in and supporting work to further understanding and increasing awareness of breast-implant-associated ALCL.***

117. Results presented from France in December 2018, further strengthened the connection between ALCL and textured breast implants. At the 2018 American Society of Hematology ("ASH") Annual Meeting in San Diego, California, researchers from Hôpital Henri Mondor, Créteil, France, shared data on BIA-ALCL collected by The Lymphoma Study Association (LYSA). LYSA began tracking ALCL cases in 2016, and since then, 50 cases have

been recorded. Information about implant type was available for 31 patients. All 31 had had at least one textured implant; 26 of these had at least one Biocell implant.

Allergan's Own Adverse Event Reporting Demonstrates Allegan's Knowledge of their Breast Implants' Link to ALCL

118. A review of adverse event reports on MAUDE involving Allergan's textured implants reveals 1,398 injury reports since 1995. Of these, 299 involved confirmed BIA-ALCL cases; another 12 involved likely cases of BIA-ALCL. There were also eight adverse event reports which involved deaths linked to Allergan's textured implants. There were four additional deaths where the cause of death was unknown, but reported to be linked to the textured implants.

119. However, the number of adverse event reports on MAUDE actually ***understates*** the extent of the problem—in part because of Allergan's reporting practices during the Class Period.

120. First, Allergan submitted a significant number of adverse event reports under incorrect manufacturer names such as "Costa Rica" or "Santa Barbara" instead of "Allergan." This made it more difficult for consumers, doctors, or the FDA to notice troubling patterns in a manufacturer's product lineup. Allergan engaged in this practice even though FDA regulations are very specific in requiring all of the following information in a specific format:

a. "Patient information (Form FDA 3500A, Block A)"

b. "Adverse event or product problem (Form FDA 3500A, Block B)"

c. "Device information (Form FDA 3500A, Block D)," including "Brand name," "Manufacturer name, city, and state," and "unique device identifier (UDI) that appears on the device label or on the device package"

d. "Initial reporter information (Form FDA 3500A, Block E)"

e. "Reporting information for all manufacturers (Form FDA 3500A, Block G)," including "Your reporting office's contact name and address and device manufacturing site" and "PMA/510k Number"

f. "Device manufacturer information (Form FDA 3500A, Block H)."

121. Second, until 2017, Allergan had been "bury[ing] evidence of ruptures and other injuries by reporting them as routine events that did not require public disclosure."[43] Specifically, instead of filing an individualized adverse event report for each adverse event, as required, Allergan had been filing "Alternative Summary Reports" for multiple adverse events at a time, which (1) require far less detail and (2) are not publicly available on MAUDE. After the FDA cracked down on this practice in 2017, "the number of suspected breast implant injuries jumped from an average of fewer than 200 a year through 2016, before the FDA's more rigorous reporting rules, to 4,567 events in 2017 and at least 8,242 in the first half of 2018." Before 2017, a "doctor's relying just on the public reports — and unaware that many incidents may be omitted" could have "easily reach[ed] the wrong conclusion about the safety record of a particular device."[44] Furthermore, "even though alternative summary reporting is supposed to be used only for events "well-known and well-documented with the FDA," Allergan submitted ***at least one case of possible BIA-ALCL through an alternative summary report***."[45] The report

[43] Sasha Chavkin, *Breast Implant Injuries Kept Hidden As New Health Threats Surface,* ICIJ—The Implant Files (Nov. 26, 2018), https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface/.

[44] Christina Jewett, *Hidden FDA Reports Detail Harm Caused By Scores Of Medical Devices*, Kaiser Health News (Mar. 7, 2019), https://khn.org/news/hidden-fda-database-medical-device-injuries-malfunctions/.

[45] *See* MAUDE Adverse Event Report: Allergan (Costa Rica), FDA, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=7521708

states "information in this report was previously submitted through asr on 22/jul/2018" and "Patient additionally reported right side anaplastic large cell lymphoma (alcl)."

MATERIALLY FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

122. In May 19, 2016, the WHO issued a guidance definitively linking breast implants to ALCL and officially naming the new disease BIA-ALCL.

123. As discussed above, a study published in January 2017 (published online on December 28, 2016) found an incidence rate for development of BIA-ALCL, in patients of Natrelle 410 implants, to be ***close to 1 in 4,000***.

124. The Class Period begins on January 30, 2017 with Defendants' first public statements regarding BIA-ALCL following the WHO's guidance and the January 2017 study.

First Quarter of 2017

125. On January 30, 2017, ABC News 7 on Your Side, published an article titled, "Woman who beat cancer once says breast implants caused cancer again." The article quotes DeSena as stating:

> Upon receiving approval for the Natrelle 410 breast implant, Allergan was required to conduct post-approval follow-up studies of approximately 3,500 patients who were enrolled in the 410 clinical study. These studies were part of the normal FDA approval process for breast implants and were not specific to BIA-ALCL. Allergan fulfilled all of its post-approval commitments in 2014 and requested FDA's approval to discontinue the studies early in light of Allergan meeting all post-approval commitments. FDA approved Allergan's request and the studies were discontinued in 2014. The discontinuation of these post-approval studies had nothing to do with BIA-ALCL. Allergan complied with standard protocols and regulations relating to the termination of the studies, which included proper notification to the trial sites and the Institutional Review Boards.
>
> The link to the FDA website provided below is to a Natrelle 410 case-control study that Allergan never conducted because FDA ultimately

deemed it unnecessary. The case-control study was designed to evaluate several rare diseases, including rare CTDs, rare neurological diseases, brain cancer, cervical/vulvar cancer, and lymphoma.

Lastly, to reiterate, ***Allergan has a robust post-market surveillance process (e.g., collecting reports of BIA-ALCL from surgeons, notifying FDA and other international regulatory agencies of all suspected cases, monitoring literature and case presentations, etc.) to monitor and report suspected cases of BIA-ALCL.***

***

Allergan continues to provide educational information regarding this disease to both physicians and patients, as well as working with the FDA and regulatory authorities to collect and assess safety reports to help inform the physician community, regulatory agencies and patients on the appropriate use of our implants…

126. Additionally, the article also quotes Marmur as stating:

Patient safety is always Allergan's first priority. However rare, Allergan takes this disease seriously.

According to the FDA, BIA-ALCL has been reported in patients with textured breast implants from all manufacturers. Because of the limited number of confirmed BIA-ALCL case worldwide, the medical community has not been able to establish causality.

Allergan is actively working to help advance the knowledge of this disease, understand the association of BIA-ALCL and textured implants, and educate the community, including:

- Working closely with the FDA and global regulatory bodies to ensure that our products' labeling documents include all information necessary for healthcare professionals and patients. This includes safety data, precautions, warnings, potential side effects. In addition, Allergan has added information on BIA-ALCL as a rare adverse event into the patient literature that accompanies every pack of implants in the US and internationally.

- Convening global medical experts and researchers to foster collaboration and advance the medical community's knowledge and awareness of the disease. Allergan also has conducted surgeon

education meetings and webcasts in the US and internationally since 2014.

- Working closely with FDA and other regulatory authorities to submit all reports of BIA-ALCL annually. Please see the FDA's web site for additional information: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm240000.htm#howtoreport;

- Supporting ongoing research to ensure physicians and patients have the latest scientific findings to appropriately diagnose and effectively treat the disease, ensuring women are appropriately informed, monitored, and managed if diagnosed with BIA-ALC.

- Partnering with ASPS, ASAPS and ISAPS to distribute BIA-ALCL educational materials and work with these societies on guidance for healthcare professionals regarding the appropriate management of patients.

127. These statements are materially false and/or misleading because Defendants Desena and Marmur, failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statements are misleading because: (i) as stated by CW2, Allergan shut down its Santa Barbara facility, which was the center for breast implant research and development; (ii) Allergan failed to report many adverse events individually and publicly and instead used inappropriately nonpublic "Alternative Summary Reports" and the Company submitted at least one case of possible BIA-ALCL through an alternative summary report; (iii) by suppressing the reporting of adverse event reports Defendants knew or recklessly disregarded the sink that some BIA-ALCL cases would go undetected by the FDA which contradicts their statements to be in compliance with FDA reporting guidelines; and (iv) as detailed in various consumer complaints, Allergan was not appropriately advising patients of the risks associated with textured breast implants and the development of BIA-ALCL. The statements are additionally misleading because Defendants Desena and Marmur, while touting Allergan's

alleged "robust post-market surveillance process," that the Company is "actively working to help advance the knowledge" of BIA-ALCL and that the Company is "providing educational information," failed to disclose: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew or, or recklessly disregarded the definitively established link between its breast implants and ALCL; (iii) and that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from the market.

128. On February 8, 2017, the Company held its Q4 2016 Earnings Call. With regards to breast implants, Defendant Saunders made the following statements: "Obviously we are going deeper into plastic surgery. We already had a very large robust business in plastic surgery with implants. I think we are doing it in a way that allows the organization to best service the customer, but also learn and get smarter."

129. This statement is materially false and/or misleading because Defendant Saunders failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statement is additionally misleading because Defendant Saunders, while touting Allergan's "very large robust business in plastic surgery with implants," failed to disclose: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew or, or recklessly disregarded the definitively established link between its breast implants and ALCL; (iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from certain markets; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

130. On February 13, 2017, the Company held a conference call to discuss the proposed acquisition of ZELTIQ by Allergan. With regards to breast implants, Defendant Meury made the following statements: "We are number one in the toxin category with Botox; number one in fillers with the Juvederm collection; number one in skincare with SkinMedica; number one in breast implants; and number one in the ADM category with ALLODERM and STRATTICE and CoolSculpting will strengthen an already very strong product line and as Brent mentioned, it is top and bottom line accretive to our business."

131. This statement is materially false and/or misleading because Defendant Meury failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statements is additionally misleading because Defendant Meury, while touting that Allergan is "number one in breast implants," failed to disclose: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew or, or recklessly disregarded the definitively established link between its breast implants and ALCL; (iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from the market; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

132. On February 24, 2017, the Company filed its annual report on Form 10-K for the 2016 (the "2016 10-K"). In the 2016 10-K, the Company stated that it "is a global specialty pharmaceutical company engaged in the development, manufacturing, marketing, and distribution of… medical aesthetics… products." Among the medical aesthetic products the Company markets and touts as a "key promoted product" are breast implants.

133. With regards to the Company's breast implant production, the 2016 10-K provides:

> Our medical device product candidates, including our breast implants, must undergo rigorous clinical testing and an extensive government regulatory clearance or approval process prior to sale in the United States and other countries. The lengthy process of clinical development and submissions for approvals, and the continuing need for compliance with applicable laws and regulations, require the expenditure of substantial resources. Regulatory clearance or approval, when and if obtained, may be limited in scope, and may significantly limit the indicated uses for which a product may be marketed. Approved products and their manufacturers are subject to ongoing review, and discovery of previously unknown problems with products may result in restrictions on their manufacture, sale, use or their withdrawal from the market.

134. After stating that its medical devices, such as breast implants, undergo a "rigorous" clinical testing and regulatory review, the 2016 10-K included the boilerplate warning that "[t]he design, development, manufacture and sale of our products involves the risk of product liability claims by consumers and other third parties, and insurance against such potential claims is expensive and may be difficult to obtain.":

> From time to time reports related to the quality and safety of breast implant devices are published, ***including reports that have suggested a possible association between anaplastic large cell lymphoma and breast implants, as well as negative reports from regulatory authorities in Europe related to a breast implant manufacturer that is not affiliated with the Company***. In addition, government investigations related to the use of products, but not the efficacy themselves, may cause reputational harm to the Company. Negative publicity, whether accurate or inaccurate, about the efficacy, safety or side effects of our products or product categories, whether involving us or a competitor, could materially reduce market acceptance to our products, cause consumers to seek alternatives to our products, result in product withdrawals and cause our stock price to decline. Negative publicity could also result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact. Any such claims, proceedings, investigations or litigation, regardless of the merits, might result in substantial costs, restrictions on product use or sales, or otherwise injure our business.

135. The Company further states in the 2016 10-K that it "provides warranty programs for breast implant sales primarily in the United States, Europe and certain other countries." For Fiscal 2016, the Company accounted for a $6.8 million provision for related warranty expenses.

136. The 2016 10-K contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, stating that the filing "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]"

137. These statements referenced in ¶¶ 132–136 are materially false and/or misleading because Defendants failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statements are misleading because Defendants touted that breast implants are a "key promoted product" and that they "must undergo rigorous clinical testing, yet: (i) as stated by CW2, Allergan shut down its Santa Barbara facility, which was the center for breast implant research and development; (ii) Allergan failed to report many adverse events individually and publicly and instead used inappropriately nonpublic "Alternative Summary Reports and the Company submitted at least one case of possible BIA-ALCL through an alternative summary report; (iii) by suppressing the reporting of adverse event reports Defendants knew or recklessly disregarded the sink that some BIA-ALCL cases would go undetected by the FDA which contradicts their statements to be in compliance with FDA reporting guidelines; and (iv) as detailed in various consumer complaints, Allergan was not appropriately advising patients of the risks associated with textured breast implants and the development of BIA-ALCL. The statements are additionally misleading because while stating that that there are "reports that have suggested a possible association between anaplastic large

cell lymphoma and breast implants," Defendants failed to disclose: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew or, or recklessly disregarded the definitively established link between its breast implants and ALCL; and (iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from certain markets.

138. On March 7, 2017, at the Cowen Health Care Conference, Defendant Saunders stated:

> One of our core therapeutic areas as medical aesthetics. We are the world leader in medical aesthetics. Today, we are basically facial aesthetics company. And before the LifeCell deal, we were facial aesthetics company with a plastic surgery business that focused on breast reconstruction augmentation. While we are very good in facial aesthetics, anchored by BOTOX aesthetic, JUVEDERM family of fillers, and then Kybella, which is emerging for submental fullness, we wanted to make sure that we were strong in each of our other pillars and could be Number 1 with durability, but also future growth. ***We became the Number 1 player in breast implants last year, just slightly ahead of J&J and Mentor.*** And so we decided that the best way to continue to innovate and expand the breast business was to support it with the regenerative medicine company LifeCell, which makes AlloDerm, which is like BOTOX of regenerative medicine for surgeons doing breast reconstruction.

139. This statement is materially false and/or misleading because Defendant Saunders failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. It is additionally misleading because Defendant Saunders, while touting that Allergan "became the Number 1 player in breast implants last year," failed to disclose: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew or, or recklessly disregarded the definitively established link between its breast implants and ALCL;

(iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from certain markets; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

Second Quarter of 2017

140. On May 14, 2017, *The New York Times* published an article titled, "A Shocking Diagnosis: Breast Implants 'Gave Me Cancer'." An Allergan spokesman, responding for comment stated in an email, "***Allergan is studying bacterial biofilms, and immune and inflammatory responses to breast implants***…. ***[T]he company took the disease seriously and was working with professional societies to distribute educational materials about it***."

141. This statement is materially false and/or misleading because Defendants failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statement is also misleading because Defendants claimed that "they are studying bacterial biofilms" and that "they took the disease seriously," yet: (i) as stated by CW2, Allergan shut down its Santa Barbara facility, which was the center for breast implant research and development; (ii) Allergan failed to report many adverse events individually and publicly and instead used inappropriately nonpublic "Alternative Summary Reports and the Company submitted at least one case of possible BIA-ALCL through an alternative summary report; (iii) by suppressing the reporting of adverse event reports Defendants knew or recklessly disregarded the sink that some BIA-ALCL cases would go undetected by the FDA which contradicts their statements to be in compliance with FDA reporting guidelines and; (iv) as detailed in various consumer complaints, Allergan was not appropriately advising patients of the risks associated with textured breast implants and the development of BIA-ALCL. The statement is additionally misleading because Defendants failed to disclose: (i) that textured breast implants manufactured

by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew or, or recklessly disregarded the definitively established link between its breast implants and ALCL; and (iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from certain markets.

Third Quarter of 2017

142. On September 7, 2017, at the Wells Fargo Healthcare Conference, Defendant Saunders stated: "In fact, the breast business has done well, particularly with the now combination, particularly on the reconstruction side with our ADM, right? With ALLODERM and the [pre-prep] procedure and the way women really want to look at reconstruction after a mastectomy. So that business is doing incredibly well. So I think we're just in a position where we now have this grocery store, if you will. We have this full menu…"

143. This statement is materially false and/or misleading because Defendant Saunders failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statement is additionally misleading because Defendant Saunders, while touting breast implants as being part of this "full menu" of products offered, failed to disclose: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew or, or recklessly disregarded the definitively established link between its breast implants and ALCL; (iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from certain markets; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

Fourth Quarter of 2017

144. On November 1, 2017, the Company held its Q3 2017 Earnings call. With respect to breast implants, Defendant Meury said: "The Plastics and Regenerative Medicine business had another strong quarter, too. Sales for ALLODERM, the Tissue Matrix for breast reconstruction and the flagship of the line are exceeding expectations. Our breast implants business also had a strong quarter, powered by the launch of 2 new premium implants, INSPIRA SoftTouch and Cohesive."

145. This statement is materially false and/or misleading because Defendant Meury failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statement is additionally misleading because Defendant Meury, while touting that Allergan's implant business had a strong quarter, failed to disclose: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew or, or recklessly disregarded the definitively established link between its breast implants and ALCL; (iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from certain markets; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

First Quarter of 2018

146. On February 6, 2018, the Company held its Q4 2017 Earnings Call. With respect to breast implants, Defendant Meury said:

> In Plastics and Regenerative Medicine, fourth quarter U.S. sales were exceptionally strong, up 15% on a pro forma basis versus last year. Growth in this segment has been driven primarily by ALLODERM, our tissue matrix for breast reconstruction, which is exceeding expectations; and market share gains for our 2 new INSPIRA breast implants. Our implant client also benefited from supply disruptions at a key competitor.

> We expect ALLODERM sales growth in 2018 will remain strong, growth for our breast implant business will moderate to low single digits.

147. This statement is materially false and/or misleading because Defendant Meury failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statement is additionally misleading because Defendant Meury, while touting expected growth for Allergan's breast implant business failed to disclose: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew or, or recklessly disregarded the definitively established link between its breast implants and ALCL; (iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from the market; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

148. On February 26, 2018, the Company filed an Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the quarter and year ended December 31, 2017 (the "2017 10-K").

149. In the 2017 10-K, the Company stated that it "markets a portfolio of leading brands and best-in-class products for the central nervous system, eye care, ***medical aesthetics*** and dermatology, gastroenterology, women's health, urology and anti-infective therapeutic categories."

150. Among the medical aesthetic products produced by the Company are breast implants. Allergan reported in the 2017 10-K net revenues from Breast Implants in the United States of $242.6 for 2017. Internationally, the Company reported net revenues of $156.9 million for 2017.

151. With regards to the Company's breast implant production, the 2017 10-K provides:

> Our medical device product candidates, including our breast implants, must undergo rigorous clinical testing and an extensive government regulatory clearance or approval process prior to sale in the United States and other countries. The lengthy process of clinical development and submissions for approvals, and the continuing need for compliance with applicable laws and regulations, require the expenditure of substantial resources. Regulatory clearance or approval, when and if obtained, may be limited in scope, and may significantly limit the indicated uses for which a product may be marketed. Approved products and their manufacturers are subject to ongoing review, and discovery of previously unknown problems with products may result in restrictions on their manufacture, sale, use or their withdrawal from the market.

152. After stating that its medical devices, such as breast implants, undergo a "rigorous" clinical testing and regulatory review, the 2017 10-K included the boilerplate warning that "[t]he design, development, manufacture and sale of our products involves the risk of product liability claims by consumers and other third parties, and insurance against such potential claims is expensive and may be difficult to obtain.":

> ***From time to time reports related to the quality and safety of breast implant devices are published, including reports that have suggested a possible association between anaplastic large cell lymphoma and breast implants, as well as negative reports from regulatory authorities in Europe related to a breast implant manufacturer that is not affiliated with the Company***. In addition, government investigations related to the use of products, but not the efficacy themselves, may cause reputational harm to the Company. Negative publicity, whether accurate or inaccurate, about the efficacy, safety or side effects of our products or product categories, whether involving us or a competitor, could materially reduce market acceptance to our products, cause consumers to seek alternatives to our products, result in product withdrawals and cause our stock price to decline. Negative publicity could also result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact. Any such claims, proceedings, investigations or litigation, regardless of the merits, might result in substantial costs, restrictions on product use or sales, or otherwise injure our business.

153. The 2017 10-K contained signed certifications pursuant to SOX by the Individual Defendants, stating that the filing "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]"

154. The statements referenced in ¶¶ 148–153 are materially false and/or misleading because Defendants failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statements are misleading because Defendants touted that breast implants "must undergo rigorous clinical testing," yet (i) as stated by CW2, Allergan shut down its Santa Barbara facility, which was the center for breast implant research and development; (ii) Allergan failed to report many adverse events individually and publicly and instead used inappropriately nonpublic "Alternative Summary Reports" and the Company submitted at least one case of possible BIA-ALCL through an alternative summary report; (iii) by suppressing the reporting of adverse event reports Defendants knew or recklessly disregarded the sink that some BIA-ALCL cases would go undetected by the FDA which contradicts their statements to be in compliance with FDA reporting guidelines; and (iv) as detailed in various consumer complaints, Allergan was not appropriately advising patients of the risks associated with textured breast implants and the development of BIA-ALCL. The statements are additionally misleading because while stating that "reports that have suggested a possible association between anaplastic large cell lymphoma and breast implants," Defendants failed to disclose: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew or, or recklessly disregarded the definitively established link between its breast

implants and ALCL; and (iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from certain markets.

155. On March 14, 2018, at the Barclays Global Healthcare Conference, with regards to breast implants, Defendant Saunders made the following statements: "I think, lastly, I would say, and there are several more reasons, but we also are a full medical aesthetics company, and we have arguably the best products in each category of medical aesthetics, whether it be body contouring, whether it be breast implants, whether it be ADMs, whether it be fillers and the like."

156. This statement is materially false and/or misleading because Defendants Saunders failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statement is additionally misleading because Defendant Saunders, while touting that Allergan has "the best products in each category," including breast implants, failed to disclose: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew or, or recklessly disregarded the definitively established link between its breast implants and ALCL; (iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from certain markets; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

157. On March 21, 2018, *The New York Times* published an article titled, "More Cases Are Reported of Unusual Cancer Linked to Breast Implants." The article reported that Marmur, said by email, ***that the Company was paying for research by outside investigators into causes of the lymphoma, working with plastic surgery societies on improved surgical techniques, adding information about the disease to its labeling and website, and giving surgeons educational materials for patients.***

158. This statement is materially false and misleading because Defendant Marmur failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statement is misleading because: (i) as stated by CW2, Allergan shut down its Santa Barbara facility, which was the center of breast implant research and development; (ii) Allergan failed to report many adverse events individually and publicly and instead used inappropriately nonpublic "Alternative Summary Reports" and the Company submitted at least one case of possible BIA-ALCL through an alternative summary report; and (iii) as detailed in various consumer complaints, Allergan was not appropriately advising patients of the risks associated with textured breast implants and the development of BIA-ALCL. The statement is additionally misleading because Defendant Marmur, while claiming that the Company was paying for outside research to investigate the causes of lymphoma, failed to disclose that: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew of, or recklessly disregarded the definitively established link between its breast implants and ALCL; and (iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from certain markets.

Second Quarter of 2018

159. On May 29, 2018, Allergan issued a press release, "Allergan Responds to Media Reports on Breast Implant Associated Anaplastic Cell Lymphoma (BIA-ALCL)," defending its decision to market the controversial textured implants:

> Allergan manufactures a broad portfolio of breast implants, including those with textured and smooth surfaces. ***To date, we are not aware of any BIA-ALCL cases that have been found with other Allergan implants in Australia and New Zealand that do not include Biocell…***

> ***The safety profile of Allergan's smooth and textured breast implants is supported by extensive pre-clinical device testing, more than a decade of U.S. and European clinical experience involving more than 160,000 women[2], as well as a large number of peer-reviewed and published studies.[2]***
>
> ***
>
> When diagnosed and treated early by a surgical specialist, BIA-ALCL has a good prognosis.[7,8] Worldwide, ***BIA-ALCL has been reported with multiple different implant manufacturers.[9-13] Direct causality has not been established with implants from a specific manufacturer.***

160. In contending that the safety of Allergan's textured implants is supported by published studies and that breast implant-associated ALCL is reported with multiple implant manufacturers, Allergan cites to published studies dating to 2008, 2011 and 2012 – two of them, Largent and de Jong, are discussed above. However, these studies were conducted when data respecting the link between textured implants and ALCL was not as well-known nor documented.

161. These statements are materially false and/or misleading because Allergan fails to cite to, and acknowledge, more recent studies from 2016 and 2017, that definitively conclude that breast implant-associated ALCL is exclusively found in textured implants and that Allergan's implants are associated with more cases than any other type of textured implant – by far. The statements are also materially false and/or misleading because Defendants failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statements are also misleading because Defendants, while claiming that the safety of "textured breast implants is supported by extensive pre-clinical device testing," failed to disclose that: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual

Defendants knew or, or recklessly disregarded the definitively established link between its breast implants and ALCL; (iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from certain markets; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

Fourth Quarter of 2018

162. On November 26, 2018, ABC News published an article titled, "Doctors, patients raise alarms about cancel linked to breast implants." The article further reported that makers of the breast implants had no immediate plans to stop selling textured versions. Allergan made the following statements:

> As with any medical procedure or device, patients considering breast implants are encouraged to have a comprehensive conversation with their surgeon about all potential risks and benefits, allowing for a fully informed decision,
>
> Based on available scientific information, global health agencies and manufacturers are not recommending any change in implant availability, current practice, post-implant care and check-ups,
>
> ***Allergan is and has been fully committed to investing in and supporting work to further understanding and increasing awareness of breast-implant-associated ALCL.***

163. This statement is materially false and/or misleading because Defendants failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL. The statements are misleading because Defendants claim to be "committed to investing in and supporting work" in connection with "awareness of" BIA-ALCL, yet: (i) as stated by CW2, Allergan shut down its Santa Barbara facility, which was the center of breast implant research and development; (ii) Allergan failed to report many adverse events individually and publicly and instead used inappropriately nonpublic "Alternative Summary Reports" and the

Company submitted at least one case of possible BIA-ALCL through an alternative summary report; (iii) by suppressing the reporting of adverse event reports Defendants knew or recklessly disregarded the sink that some BIA-ALCL cases would go undetected by the FDA which contradicts their statements to be in compliance with FDA reporting guidelines and; (iv) as detailed in various consumer complaints, Allergan was not appropriately advising patients of the risks associated with textured breast implants and the development of BIA-ALCL. The statements are also misleading because Defendants, while claiming that the safety of "textured breast implants is supported by extensive pre-clinical device testing," failed to disclose that: (i) that textured breast implants manufactured by Allergan were definitively linked to ALCL as demonstrated in published medical studies; (ii) that the Company and the Individual Defendants knew or, or recklessly disregarded the definitively established link between its breast implants and ALCL; and (iii) that the foregoing link to cancer, when revealed, would foreseeably force Allergan to recall those textured breast implants from certain markets.

THE TRUTH BEGINS TO EMERGE

The December 2018 Recall

164. On December 18, 2018, France's National Agency for the ANSM ordered the recall of textured breast implants manufactured by Allergan from the European market, stating that the implants "have been linked to a rare form of cancer"—specifically, ALCL.

165. On December 19, 2018, Allergan issued a press release stating that it would cease selling textured breast implants in Europe. In particular, the Company stated that it "has suspended sales of textured breast implants and tissue expanders and is withdrawing any remaining supply in European markets" following a compulsory recall request by the ANSM.

166. This disclosure was the first time the Company acknowledged that its prior statements telling investors that its breast implants were not reported to be linked to ALCL in Europe were not accurate.

167. Following these announcements, Allergan's stock price fell $10.20, or nearly 7%, to close at $136.56 on December 19, 2018.

168. Information regarding the link between breast implants and the development of ALCL has continued to emerge even after the ANSM's decision, on December 18, 2018, to recall textured breast implants manufactured by Allergan. This information further demonstrates that the link was widely known to Allergan and other manufacturers.

169. For example, on January 16, 2019, the ASPS reported that there are 673 worldwide cases of breast implant-associated ALCL as of January 16, 2019 (ASPS, 2019), with 16 disease-related deaths (ASPS, 2018).

170. In February 6, 2019, the FDA issued an update which reported a total number of 660 MDRs received as of September 2018. Of the 660 MDRs, the FDA determined that there were 457 unique cases of ALCL, including 9 patient deaths.

The FDA's March 2019 Public Meeting

171. On February 11, 2019, the FDA announced that it would hold a two-day public advisory committee meeting of the General and Plastic Surgery Devices Panel which would be held on March 25-26, 2019 ("Public Meeting"). The general function of the meeting was to discuss and make recommendations regarding the benefits and risks of breast implants for achieving breast augmentation and reconstruction. The first day of the Public Meeting focused on the currently available information regarding BIA-ALCL. Information disclosed at the Public

Meeting provides more proof that Allergan had access, for years, to information respecting the established link between breast implants and ALCL.

172. In connection with the Public Meeting, the FDA released the latest information it had accumulated on the incidence of BIA-ALCL. The FDA reported a total of 457 distinct MDRs for BIA-ALCL. There were 9 deaths identified from 12 individual MDRs (i.e., three women had bilateral implants). FDA staff identified 334 reports that 15 provided information on the implant surface. Of these, 310 concerned textured implants and 24 concerned smooth implants.

173. At the Public Meeting, the FDA also reported that from August 2012 to March 2018, a total of 186 distinct cases of BIA-ALCL in the United States were reported to PROFILE. At the time of diagnosis, 69 patients (78%) had an implant with a textured shell; in 5 cases (6%) the implant type was smooth. In 15 (16%) cases the texture of the device was not reported.

174. At the Public Meeting, the FDA's Dr. Binita Ashar, M.D., Center for Devices and Radiological Health ("CDRH") Supervisory Medical Officer, noted that several notable actions taken by international regulators had prompted the Public Meeting and stated that since 2011 the FDA had been providing regular updates of reported cases of ALCL through the MDRs. Dr. Josef Zundorf, M.D., a member of an EU Task Force established to share information about the link between breast implants and ALCL, reported that to-date they had recorded approximately 800 cases of breast implant-associated ALCL worldwide. Dr. Amanda Jones from Health Canada reported that they had received 28 confirmed ALCL cases and 28 suspected – all implants were textured implants.

175. Dr. Nilsa Loyo-Berrios, from the FDA's Division of Epidemiology, CDRH, reported that in 2011 the FDA recognized that due to very low patient follow-up, post-market

studies – which were a condition for breast implant market approval – did not provide sufficient evidence on the long-term performance of the implants. An FDA panel was tasked with providing long-term study limitations and monitoring guidance. The panel recommended changes to the large study in order make it easier for patients to complete the study and to aggregate data across manufacturers. Following the recommendation, the large study was redesigned with smaller studies recommended for each manufacturer and meant to capture data for their 2006 implants as well as the more recent models approved in 2012 and 2013. Additionally, each manufacturer also conducted a large study.

176. Dr. Stephanie Mason Brown, M.D., Vice President Clinical Development at Allergan, presented on Allergan's post-approval studies at the Public Meeting. Allergan's presentation of its data further demonstrates that Allergan had access to material information respecting breast implant-associated ALCL which the Company never disclosed.

177. Dr. Mason Brown stated that following the 2011 FDA guidance, Allergan established a post-marketing monitoring program which consisted of: 1) Post-marketing surveillance; 2) NBIR; and 3) Post-approval study. The post-marketing surveillance consisted of medical assessment of adverse event reports from patients, surgeons and literature as well as evaluation of safety trends. The NBIR was used to collect baseline implant data. Allergan reported that they have one on-going post-approval study which consists of three arms: 1) Breast Implant Follow-Up Study ("BIFS") which collects round implant data; 2) 410 which collects anatomically-shaped implant data; and 3) NBIR which collects data on re-operations. There are more than 53,000 patients enrolled in the three arms and patients enrolled complete annual questionnaires and return for follow-ups post-implantation.

178. Dr. Brown Mason defended Allergan's use of textured implants by highlighting its benefits (i.e. lower incidence of capsular contracture) and emphasizing the alleged "rare occurrence of BIA-ALCL, with excellent prognosis if identified early and appropriately treated." She also stated that "the etiology of BIA-ALCL" "is not fully understood" and that "higher implant surface area may be a risk factor." Furthermore, she reported on the incidence rates in textured implants as demonstrated by the literature – USA = 1:30,000 – 1:50,000; Australia = 1:2,800 – 1:86,000; Italy = 1:28,000; Netherlands = 1:25,000. ***More importantly, Dr. Brown Mason reported shockingly high incidence rates in Allergan's Biocell textured implants as determined by Allergan's own post-market studies. The 410 CA/CARE Study, found the incidence rate in the US to be 1:3,000; the US Biocell Rate was determined to be 1:16,000 and the Worldwide Biocell Rate was 1:32,000. Allergan further admitted that these rates are higher than those reported by any other manufacturer.***

179. Finally, Dr. Brown Mason claimed that Allergan was conducting internal research and was supporting external research into BIA-ALCL. Allergan claimed to be supporting independent research into immunology, looking into the causes of ALCL and genetic associations. Internally, Allergan claimed to be conducting research into the impact of infection control and into development of lower surface area textured implants. As discussed *supra* ¶¶ 95–97, it is unclear how Allergan purports to be conducting internal research when it has eviscerated its breast research department.

ADDITIONAL SCIENTER ALLEGATIONS

180. Individual Defendants Bisaro and Meury each derived a concrete and personal benefit from concealing material adverse facts concerning the known link between Allergan's textured breast implants and the development of BIA-ALCL. As the chart below reflects, during

the Class Period, while the Company's share price was inflated artificially due to Defendants' materially false and misleading statements and omissions, Defendants Bisaro and Meury collectively unloaded 165,111 shares of their Allergan stock for total proceeds of approximately $28.7 million.

181. Furthermore, Defendants Bisaro and Meury sold their shares at suspicious times. Defendant Bisaro sold 70,000 shares of Allergan stock on March 2, 2017, for proceeds of $17.2 million. This was a little over *two weeks* after Defendant Bisaro touted on a February 13, 2017 conference call that Allergan's breast implant business was "number one." This was also approximately *one week* after the Company filed its 2016 10-K, on February 24, 2017, touting that their breast implants, undergo a "rigorous" clinical testing and regulatory review and stating that reports merely "suggested" a possible link between breast implants and BIA-ALCL. These were market sales not pursuant to a 10b5-1 trading plan.

182. Defendant Meury sold 11,807 shares of Allergan stock on December 1, 2017, for proceeds of approximately $1,000,000. This was *one month* after Allergan held its Q3 2017 earnings call, on November 1, 2017, where Defendant Meury touted that their implants business had a strong quarter. These were market sales not pursuant to a 10b5-1 trading plan.

183. Defendant Meury sold 58,879 shares (23,613 from exercised options, which were not due to expire until December of 2019) on February 14, 2018, for net proceeds of almost $8 million. This was approximately *one week* after Allergan held its Q4 2017 earnings call, on February 6, 2018, where Defendant Meury touted that sales in their plastics and regenerative medicine business were up 15% and that growth in the breast implant business would continue. These were market sales not pursuant to a 10b5-1 trading plan.

184. Defendant Meury sold 24,425 shares (21,252 from exercised options) on May 17, 2018, for net proceeds of $2.3 million. Defendant Meury sold approximately *two months* after Defendant Marmur made a statement, published in a March 21, 2018 *The New York Times* article, stating that the Company was paying for research into the causes of lymphoma. While Defendant Meury sold pursuant to a 10b5-1 trading plan, the plan had only been established on November 16, 2017 – well into the time period when Defendants had access and knowledge of the link between the Allergan textured breast implants and BIA-ALCL.

CLASS ACTION ALLEGATIONS

185. Lead Plaintiff brings this action as a class action under Federal Rule of Civil Procedure 23(a) and (b)(3), individually and on behalf of all those who purchased or otherwise acquired the Company's securities during the Class Period. Excluded from the Class are Defendants, the officers and directors of the Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

186. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's securities were actively traded on NYSE. While the exact number of Class members is unknown at this time and can be ascertained only through appropriate discovery, Lead Plaintiff believe there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by the Company's or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

187. Lead Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

188. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

189. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. Whether Defendants violated the Exchange Act;

b. Whether Defendants participated in and pursued the wrongful activities complained of herein;

c. Whether Defendants' statements were materially false and misleading or omitted to state material facts about the Company;

d. Whether Defendants acted with due care in misrepresenting or omitting to state material information concerning the Company; and

e. The extent of damages sustained by members of the Class and the appropriate measure of damages.

190. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually

redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

191. Defendants have acted on grounds generally applicable to the Class with respect to the matters complained of herein, thereby making appropriate the relief sought herein with respect to the Class as a whole.

192. The questions of law or fact common to the Class predominate over any questions affecting individual members of the Class, such that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy. There will be no difficulty in managing this action as a class action.

COUNT I

Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Against All Defendants

193. Lead Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

194. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of the Company's securities; and (iii) cause Plaintiff and other members of the Class to purchase or

otherwise acquire the Company's securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

195. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for the Company's securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company's finances and business prospects.

196. By virtue of their positions at the Company, defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

197. Information showing that defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of the Company, the Individual Defendants had knowledge of the details of the Company's internal affairs.

198. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the Company. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to the Company's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading public statements, the market price of the Company's securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by defendants, Plaintiff and the other members of the Class purchased or otherwise acquired the Company's securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by defendants, and were damaged thereby.

199. During the Class Period, the Company's securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of the Company's securities at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of the Company's securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of the Company's

securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

200. By reason of the conduct alleged herein, defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

201. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Violations of Section 20(a) of the Exchange Act against the Individual Defendants

202. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

203. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about the Company.

204. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

205. Because of their positions of control and authority as senior officers, the Individual Defendants were able to and did control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period concerning the Company's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of the Company's securities.

206. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

207. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

a. Determining that the instant action may be maintained as a class action under Federal Rule of Civil Procedure 23, and certifying Lead Plaintiff as Class Representatives;

b. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

c. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

d. Awarding such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury.

Dated: April 19, 2019

/s/ Jeremy A. Lieberman

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